

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

No. 02 Civ. 8448 (RJS)
No. 03 Civ. 3816 (RJS)
No. 03 Civ. 3817 (RJS)
No. 03 Civ. 3819 (RJS)
No. 03 Civ. 8907 (RJS)
No. 04 Civ. 1555 (RJS)
No. 04 Civ. 4046 (RJS)

ENZO BIOCHEM, INC., *ET UNO*,

Plaintiffs,

VERSUS

AMERSHAM PLC, *ET AL.*,

Defendants.

AND RELATED CASES NAMING:

MOLECULAR PROBES, INC., *ET AL.*, PERKINELMER, INC., *ET AL.*,
ORCHID BIOSCIENCES, INC., *ET AL.*, AFFYMETRIX, INC., AND
ROCHE DIAGNOSTICS GMBH, *ET AL.*

MEMORANDUM AND ORDER
September 21, 2012

RICHARD J. SULLIVAN, District Judge.

Plaintiffs Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (collectively “Enzo” or “Plaintiffs”) bring these actions for patent

infringement against Defendants.¹ Before the Court is Defendants’ joint motion for

¹ Defendants are Affymetrix, Inc. (“Affymetrix”), Amersham plc, Amersham Biosciences (collectively “Amersham”), Molecular Probes, Inc., Orchid

summary judgment that some of the accused products (1) do not infringe U.S. Patent Nos. 4,994,373 (the “’373 Patent”), 5,328,824 (the “’824 Patent”), and 5,449,767 (the “’767 Patent”), either literally or under the doctrine of equivalents, and (2) do not infringe certain other patents because they were manufactured with Plaintiffs’ authorization. Defendants also move for summary judgment on Plaintiffs’ claims under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). For the reasons that follow, the Court grants in part and denies in part Defendants’ motion.

I. BACKGROUND

At the heart of these actions are a series of patents that cover reagents² used in connection with the labeling and testing of DNA. The Court assumes the parties familiarity with the complex chemistry that underlies these patents as well as the products manufactured by Defendants that are accused of infringing. Accordingly, the Court provides only a brief summary of the technology necessary to explain its rulings on the instant motion.

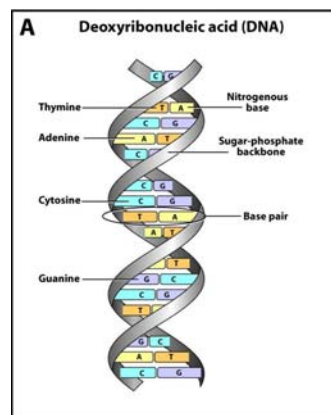
A. Factual Background

DNA is a nucleic acid, which is made up of different sequences of four chemical building blocks known as nucleotides. Nucleotides contain one of four different bases: adenine (“A”), cytosine (“C”), guanine (“G”), and thymine (“T”). (Def.’s

Biosciences, Inc., PerkinElmer Life Sciences, Inc., PerkinElmer, Inc. (collectively “PerkinElmer”), Roche Diagnostics GmbH, and Roche Molecular Systems, Inc. (collectively “Roche”).

² Reagents are chemical substances that are added to chemical systems to bring about a chemical reaction or determine if a reaction occurred in that system. (*Reactant*, Compendium of Chemical Terminology, <http://goldbook.iupac.org/R05163.html>.)

Br. 3-4.)³ To form the traditional double-stranded form, the sequence of nucleotides in each strand must be complementary – for instance, As bond with Ts, and Gs pair with Cs, as shown in the diagram below:



(Def.’s Br. 2.) Determining the particular sequence of nucleotides in a sample of DNA is important for the detection of genetic diseases and is also widely used in research, such as in connection with sequencing the human genome. (Opp’n 3-4.)

Although these lawsuits involve several patents, this motion involves only three: the ’824 Patent, the ’767 Patent, and the ’373 Patent. The ’373 Patent discloses a method for detecting the presence of a certain nucleotide sequence in a sample of DNA.

³ The following facts are drawn primarily from the Court’s July 10, 2006 Claim Construction Opinion (“Claim Constr. Op.”), the parties’ Local Civil Rule 56.1 Statements (“56.1 Stmt.”), the declarations submitted in connection with the instant motion, and the exhibits attached thereto. The facts are undisputed unless otherwise noted. Where only one party’s 56.1 Statement is cited, the facts are taken from that party’s statement, and the other party does not dispute the fact asserted or has offered no admissible evidence to refute that fact. The Court also relies on general background information about the patented products that is set forth in the parties’ briefs for matters that are not directly relevant to the instant motions but helpful in order to provide context.

The test method described in this patent involves separating the DNA sample into its two strands and determining whether the unknown sample will bond, or hybridize, with a known nucleotide sequence. Because DNA nucleotides are microscopic, detectable labels are often attached to the nucleotides so that the presence of the labeled nucleotides can later be more easily detected. The labeling process is roughly analogous to how one would place a Post-it note on a pertinent page of a document to locate it later more easily. The '824 Patent and the '767 Patent share a common specification and explain, in pertinent part, how to modify nucleotides and attach detectable labels.

B. Procedural History

Plaintiff commenced the first of these actions on October 23, 2002, and it was initially assigned to the Honorable John E. Sprizzo, District Judge. The parties engaged in extensive briefing and Judge Sprizzo held a five-day *Markman* hearing before issuing a detailed opinion on July 10, 2006, which construed disputed portions of certain patent claims. Defendants then moved for summary judgment, and Judge Sprizzo held argument on those motions on July 17 and 18, 2007. Before ruling on the pending summary judgment motions, Judge Sprizzo passed away, and the cases were subsequently reassigned to my docket on January 8, 2009.

The Court held a conference on March 13, 2009 and denied the pending motions without prejudice to renewal at a future date. The Court also stayed these actions in light of a pending appeal before the Federal Circuit in a case that originated in the District of Connecticut and involved many of the same patents. Following the conclusion of that appeal, *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325 (Fed.

Cir. 2010), on August 16, 2011, the Court lifted the stay and set a briefing schedule for Defendants' renewed motions for summary judgment. The Court allowed Defendants to file motions for summary judgment on patent issues related to non-infringement only. Defendants then filed the instant joint motion for summary judgment on October 11, 2011, which was fully submitted as of January 13, 2012.

C. Claim Construction

Plaintiffs' opposition brief places great emphasis on the claim construction ruling by the Honorable Janet Arterton, District Judge, in the related action in the District of Connecticut, as well as the subsequent decision by the Federal Circuit in that matter. (Opp'n 8-11.) However, Judge Sprizzo previously denied repeated requests for reconsideration and attempts to relitigate the claim construction in these actions. After the Federal Circuit's decision in the related case, this Court specifically rejected Plaintiffs' request to "relitigate issues of claim construction that were decided by Judge Sprizzo in 2006." (Doc. No. 248 at 3.) The Court once again reaffirms its earlier conclusion that it "sees no reason to revisit such matters and finds nothing in the Federal Circuit's 2010 ruling that compels, or even suggests, such a result." (*Id.*) Accordingly, the Court will proceed to address the instant motion for summary judgment in accordance with the claim construction issued by Judge Sprizzo.

II. LEGAL STANDARD

The standard for summary judgment is well settled. Pursuant to Rule 56(a) of the Federal Rules of Civil Procedure, summary judgment should be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R.

Civ. P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The moving party bears the burden of proving that there is no genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986). Once the moving party has met its burden, the nonmoving party “must come forward with specific facts showing that there is a *genuine issue for trial*.” *Caldarola v. Calabrese*, 298 F.3d 156, 160 (2d Cir. 2002) (internal citations and quotation marks omitted).

In ruling on a motion for summary judgment, the court must resolve any ambiguity in favor of the nonmoving party. *Amnesty Am. v. Town of W. Hartford*, 361 F.3d 113, 122 (2d Cir. 2004). The court “is not to weigh the evidence but is instead required to view the evidence in the light most favorable to the party opposing summary judgment, to draw all reasonable inferences in favor of that party, and to eschew credibility assessments.” *Weyant v. Okst*, 101 F.3d 845, 852 (2d Cir. 1996). As a result, summary judgment will not issue where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson*, 477 U.S. at 248. However, “a complete failure of proof concerning an essential element of the nonmoving party’s case” renders summary judgment proper. *Celotex*, 477 U.S. at 323.

III. PATENT MARKING ESTOPPEL

As an initial matter, Plaintiffs argue that, regardless of what the patents cover and how the accused products operate, Defendants should be estopped from arguing that certain products, which they had marked as being covered by certain Enzo patent numbers, do not infringe those patents. Under the doctrine of “patent marking estoppel,” a party who “knowingly and deliberately marks its product with a patent number for a period of years, thereby

representing to the public that the product is covered by the patent,” may be prevented from later denying that the product infringes the patent with which it was marked. *Elite Licensing, Inc. v. Thomas Plastics, Inc.*, 250 F. Supp. 2d 372, 385 (S.D.N.Y. 2003); *see Boyd v. Schildkraut Giftware Corp.*, 936 F.2d 76, 79 (2d Cir. 1991). The Federal Circuit has declined to explicitly address the viability of this doctrine, but noted that “[t]he doctrine of marking estoppel, like other varieties of estoppel, should arise only when a consideration of all aspects of a defendant’s pertinent conduct makes it inequitable for him to take a position contrary to his prior statements or actions.” *Slip Track Sys., Inc. v. Metal Lite, Inc.*, 113 F. App’x 930, 934 (Fed. Cir. 2004) (quoting *Boyd*, 936 F.2d at 79) (internal quotation marks and alterations omitted).

Regardless of whether patent marking estoppel is viable, the record is not sufficiently developed for the Court to determine whether this equitable doctrine should be applied in this case. *Cf. High Frequency Prods., Inc. v. Wynn’s Climate Sys., Inc.*, 91 F.3d 167, No. 95-1468, 1996 WL 217840, at *2 (Fed. Cir. 1996) (declining to address the viability of patent marking estoppel but affirming district court’s finding that defendants were not estopped from denying infringement based on the facts of the particular case). Here, Plaintiffs assert only that “Defendants knowingly and deliberately marked specific products with Enzo’s patent numbers, and for years benefitted therefrom.” (Opp’n 20.) However, with the exception of noting which products were so marked (Decl. of Justin A. MacLean, dated Dec. 13, 2011, Doc. No. 267 (“MacLean Decl.”), Ex. 41; Pl.’s 56.1 ¶ 77), Plaintiffs do not identify with specificity any facts from which the Court can conclude that Defendants should be estopped from denying infringement. For example, there is no indication of how long

or why Defendants marked these products with Enzo patent numbers. *Cf., e.g., Rainworks Ltd. v. Mill-Rose Co.*, 609 F. Supp. 2d 732, 740 (N.D. Ohio 2009) (recognizing that defendants marked their products with the patent number that they were accused of infringing for a significant period of time but concluding that, in equity, the doctrine did not foreclose defendants' defenses and non-infringement counterclaims). Accordingly, the Court, sitting in equity, cannot conclude that Defendants are estopped from denying infringement simply because they marked certain products with Enzo patent numbers.

IV. THE '373 PATENT

Defendants Affymetrix, Amersham, PerkinElmer, and Roche argue that they are entitled to summary judgment of non-infringement of the '373 Patent because certain of their products (the "Accused '373 Products")⁴ do not meet two of the limitations in Claim 1. Specifically, Defendants assert that Claim 1 of the '373 Patent covers only the specific test format in which the probe is labeled and the sample is fixed to a solid support, while the Accused '373 Products use the inverse arrangement, in which the probe is fixed and the sample is labeled. (Def.'s Br. 29-30.) Additionally, Defendants assert that the Accused '373 Products do not meet the "soluble signal" limitation of the patent. (*Id.* at 32.) The Court addresses whether the Accused '373 Products meet either of these limitations after briefly describing the background of the invention.

A. Background

The '373 Patent involves the determination of whether nucleotide sequences known as "analytes" are present in certain non-biological or biological samples such as blood, saliva, or other tissue samples. ('373 Patent col.5, ll.22-27; Claim Constr. Op. 18; Def.'s 56.1 ¶ 35.) The patent discloses a procedure whereby DNA strands are denatured, or separated, into single-stranded form and attached to a solid surface. ('373 Patent col.5, ll.37-41; Claim Constr. Op. 18-19.) These denatured strands are referred to as the "sample." (Def.'s 56.1 ¶ 36; Pl.'s 56.1 ¶ 36.) A probe, which is a single-stranded DNA sequence that contains a sequence complementary to the analyte, is then introduced. (Def.'s 56.1 ¶ 36; Pl.'s 56.1 ¶ 36.) If the sample contains the analyte, the probe will bind, or hybridize, with the sample. (Def.'s 56.1 ¶ 36; Pl.'s 56.1 ¶ 36.) To determine whether hybridization occurred and whether the sample contains the analyte, the patent discloses a washing step to remove the unhybridized probes. (Def.'s Br. 24; Gunther Decl. Ex. 14 ¶ 20.) The patent then instructs how to detect those probes that did hybridize by means of a "soluble signal." (Def.'s Br. 24-25; Claim Constr. Op. 20.)

The '373 Patent describes a "soluble signal" as "a system whereby an enzyme or other reagent reacts with a chromogen or substrate to produce a product dissolved in solution that makes its presence known by fluorescing or creating a color change which can be measured by a spectrophotometer or the like." (Claim Constr. Op. 21 (citing '373 Patent col.6, ll.4-65, col.7, ll.7-36, col.8, ll.50-56) (internal quotation marks omitted).) As Judge Sprizzo concluded during claim construction, the "tethered fluorescent molecules and other signals generated by non-dissolved molecules are

⁴ A complete list of these products is set forth in Exhibit 34 to the Gunther Declaration. (Decl. of Robert J. Gunther, Jr., dated Oct. 11, 2011, Doc. No. 253 ("Gunther Decl."), Ex. 34.)

outside the scope of this claim.” (Claim Constr. Op. at 22.)

B. Testing Format

Plaintiffs do not dispute that the Accused '373 Products do not literally infringe Claim 1 of the '373 Patent, based on the Court's claim construction that requires “the sample, which is the substance within which one is looking for the presence of the analyte, must be fixed to the solid support, and that the probe, which is a labeled sequence complementary to the analyte, cannot be so fixed.” (Opp'n 34 (quoting Claim Constr. Op. 24); Def. 56.1 ¶ 37; Pl. 56.1 ¶ 37.) However, Plaintiffs argue that the Accused '373 Products nonetheless infringe under the “doctrine of equivalents.”

Under the doctrine of equivalents, a product that does not literally infringe a patent claim may nonetheless be found to infringe if the accused product is equivalent to the subject claimed in the patent. *See, e.g., Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). “Although equivalence is a factual matter normally reserved for a fact-finder, the trial court should grant summary judgment in any case where no reasonable fact-finder could find equivalence.” *Overhead Door Corp. v. Chamberlain Grp., Inc.*, 194 F.3d 1261, 1269 (Fed. Cir. 1999) (citation and internal quotation marks omitted).

A patentee may establish infringement under the doctrine of equivalents by applying the “function-way-result test,” which considers “whether an element of an accused product performs substantially the same function in substantially the same way to obtain the same result as an element of the patented invention.” *Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318, 1338 (Fed. Cir. 2011) (citation and internal quotation marks omitted). When relying on

the doctrine of equivalents to oppose a motion for summary judgment of non-infringement, “a patentee must provide particularized testimony and linking argument as to the insubstantiality of the differences between the claimed invention and the accused device or process,” or, when appropriate, the function-way-result test. *AquaTex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320, 1328 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

Because “the doctrine of equivalents necessarily adds uncertainty to the scope of patent claims, and thereby detracts from the public-notice function of patent claims and risks deterring non-infringing and potentially innovative endeavors,” courts have developed rules that “constrain when and how the doctrine of equivalents is to be applied.” *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005) (citing *Festo Corp. v. Skoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 727 (2002)). In particular, the “all-elements rule” provides “that an accused product or process is not infringing unless it contains each limitation of the claim, either literally or by an equivalent.” *Id.* Furthermore, “an element of an accused product or process is not, as a matter of law, equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation.” *Id.* “[C]ourts must consider the totality of the circumstances of each case and determine whether the alleged equivalent can be fairly characterized as an insubstantial change from the claimed subject matter without rendering the pertinent limitation meaningless.” *Id.* at 1359.

For example, in *Ethicon Endo-Surgery v. U.S. Surgical Corp.*, the Federal Circuit affirmed a grant of summary judgment of non-infringement under the doctrine of

equivalents with respect to a patent claim relating to a “lockout mechanism” in surgical staplers. 149 F.3d 1309, 1318-19 (Fed. Cir. 1998). The Federal Circuit concluded that the claim limitation required that the lockout mechanism be in a specific place, while the accused product placed the lockout mechanism nowhere near that specific location. *Id.* at 1318. Accordingly, the Court concluded that no reasonable juror could find equivalence between the two products. *Id.* at 1319; *cf.*, *e.g.*, *Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) (refusing to find infringement under the doctrine of equivalents because “it would defy logic to conclude that a minority – the very antithesis of a majority – could be insubstantially different from a claim limitation requiring a majority, and no reasonable juror could find otherwise”); *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424-25 (Fed. Cir. 1997) (affirming grant of summary judgment of no infringement under the doctrine of equivalents because patent claimed a slot at the top of the container, and accused product placed slot inside the container). Similarly, in *Asyst Techs., Inc. v. Emtrak, Inc.*, the Federal Circuit affirmed a grant of summary judgment of non-infringement because the “doctrine of equivalents cannot be extended to reach an ‘unmounted’ system such as the [accused product] without vitiating the ‘mounted on’ limitation.” 402 F.3d 1188, 1195 (Fed. Cir. 2005).

Here, the ’373 Patent specifically claims a format in which the unlabeled sample is attached to a solid support and the labeled probe is unfixed. (Claim Constr. Op. 19-20.) However, the Accused ’373 Products use the exact opposite arrangement. (Def.’s 56.1 ¶¶ 39-41; Pl.’s 56.1 ¶¶ 39-41.) To now find that the Accused ’373 Products infringe under the doctrine of equivalents would vitiate the specific arrangement disclosed in

Claim 1 of the ’373 Patent, which the Court cannot do.

Indeed, Plaintiffs’ recognition that the possibility of reversing the arrangement of the probe and sample was known at the time that they drafted the ’373 Patent further counsels against using the doctrine of equivalents to now claim this reciprocal arrangement. “[A]s between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure.” *Sage Prods.*, 126 F.3d at 1425. Specifically, the court in *Sage Products* held that:

[a] skilled patent drafter would foresee the limiting potential of the “over said slot” limitation. No subtlety of language or complexity of the technology, nor any subsequent change in the state of the art, such as later-developed technology, obfuscated the significance of this limitation at the time of its incorporation into the claim. If [the patentee] desired broad patent protection for any container that performed a function similar to its claimed container, it could have sought claims with fewer structural encumbrances. . . . Instead, [the patentee] left the PTO with manifestly limited claims that it now seeks to expand through the doctrine of equivalents.

Id. at 1425; *see also Freedman Seating*, 420 F.3d at 1362 (reversing grant of summary judgment in favor of patentee and remanding for grant of summary judgment of non-infringement because the patentee “chose to specifically limit the claims” to a particular physical embodiment and

“[m]embers of the public were therefore justified in relying on this specific language in assessing the bounds of the claim”).

Although not claimed in the '373 Patent, Example 5 to that patent specifically notes that “[t]he advantages of this invention are also obtainable when the probe is immobilized.” ('373 Patent col.10, ll.55-57.) Thus, the Court finds that because the '373 Patent discusses, but does not claim, the arrangement of probe and analyte used in the Accused '373 Products, Plaintiffs cannot now expand the claims to incorporate that material through the doctrine of equivalents.

Moreover, Plaintiffs acknowledge that the probe and analyte arrangement used by Defendants was known at the time that they submitted this patent application, which further suggests that the doctrine of equivalents cannot be used to now capture that design. Dr. Archibald Perkins, Plaintiffs' expert, opines that, “[a]t the time the '373 application was filed, . . . the concept of immobilizing a ‘probe’ and labeling the analyte was widely known by persons in the field.” (Decl. of Archibald Perkins, dated Dec. 9, 2011, Doc. No. 264 (“Perkins Decl.”), ¶ 38.) Additionally, Dr. Perkins refers to a specific test, which was state-of-the-art at the time of the '373 application and used a fixed probe and an untethered analyte. (*Id.* ¶ 44.) Accordingly, because the reciprocal arrangement, which Defendants use and which Plaintiffs now seek to incorporate through the doctrine of equivalents, was known at the time of the '373 Patent application but not claimed, the Court further concludes that the Accused '373 Products do not infringe the '373 Patent under the doctrine of equivalents.

C. Soluble Signal

Additionally, Defendants argue that the Accused '373 Products do not infringe the '373 Patent, either literally or under the doctrine of equivalents, for the independent reason that they do not meet the “soluble signal” limitation. (Def.'s Br. 32.) Plaintiffs disagree and argue that the products literally infringe or, in the alternative, infringe under the doctrine of equivalents. (Opp'n 40-41.) The Court addresses each contention in turn.

1. Literal Infringement

The Court previously concluded that “soluble signal,” as used in the '373 Patent, “requires a soluble product which generates a detectable signal. As such, tethered fluorescent molecules and other signals generated by non-dissolved molecules are outside the scope of this claim.” (Claim Constr. Op. 22.) Nevertheless, Plaintiffs argue that the products literally infringe Claim 1 of the '373 Patent because “[t]he signal never precipitates and, thus, is not ‘insoluble.’ Rather, it is a ‘soluble signal’ in the form of light photons that are uniformly dispersed in solution and detected by a spectrophotometer.” (Opp'n 40 (internal citations omitted).) However, this argument completely ignores the Court's claim construction, which *expressly* held that the tethered fluorescent molecules used by Defendants do not fall within the literal terms of the patent. (Claim Constr. Op. 21.) Thus, because there is no dispute that the Accused '373 Products use tethered fluorescent molecules (Def.'s 56.1 ¶ 47; Pl.'s 56.1 ¶ 47), which were specifically exempted from the literal terms of Claim 1 of the '373 Patent, Defendants are entitled to summary judgment that the Accused '373 Products do not literally infringe.

2. Doctrine of Equivalents

Alternatively, Plaintiffs argue that Defendants' motion for summary judgment should be denied because the Accused '373 Products infringe under the doctrine of equivalents. Plaintiffs apply the function-way-result test and argue that the Accused '373 Products perform substantially the same function in substantially the same way to obtain the same result as an element of the patented invention. (Opp'n 41.)

Plaintiffs rely on the opinion of Dr. Perkins in support of their argument that the use of tethered fluorescent molecules by the Accused '373 Products satisfies the function-way-result test. (Opp'n 41 (citing Perkins Decl. ¶ 30).) However, Dr. Perkins's conclusory assertions fail to provide the "particularized testimony and linking argument as to" how the accused devices perform the same function in the same way to achieve the same result as the claimed invention. *AquaTex Indus.*, 479 F.3d at 1328; *cf. Nikken USA, Inc. v. Robinsons-May, Inc.*, 51 F. App'x 874, 880-81 (Fed. Cir. 2002) (affirming grant of summary judgment of non-infringement because the patentee made "only conclusory statements regarding equivalence"). Here, Dr. Perkins asserts in only the most general fashion that the fluorescent molecules perform essentially the same role as the soluble signal disclosed in the patent. (Perkins Decl. ¶ 30.) Without more particularized factual support and argument about the similarities between the soluble signals disclosed in the patent and the labels employed in the Accused '373 Patents, the Court cannot conclude that there is a material question of fact as to whether these products infringe under the doctrine of equivalents.

Additionally, Plaintiffs have not adequately established that there is a

question as to whether a person skilled in the art would understand that the tethered fluorescent molecules are interchangeable with the soluble signals specifically claimed in the '373 Patent. The Federal Circuit has explained that evidence that a structure used in an accused product is known to be interchangeable with the structure in the patent is an important factor to consider when determining if a product infringes under the doctrine of equivalents. *See, e.g., Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1370 (Fed. Cir. 2010). In support of their interchangeability argument, Plaintiffs cite only to their expert's *ipse dixit* that a person of ordinary skill in the art would find that the tethered fluorescent molecules are interchangeable with the soluble signal limitation disclosed in the patent based on certain references in the patent to fluorescent signals. (Perkins Decl. ¶ 31.) However, these conclusory allegations are insufficient to meet Plaintiffs' burden to establish facts that support a finding of infringement under the doctrine of equivalents. *Cf. Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1365 (Fed. Cir. 2007) (affirming grant of summary judgment of non-infringement because plaintiff's expert's assertion that the accused products "were not 'significantly different'" is insufficient to defeat summary judgment); *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1382 (Fed. Cir. 2007) (affirming grant of summary judgment of non-infringement because the patentee "did not provide any particularized testimony to show infringement under the doctrine of equivalents"); *TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1371-72 (Fed. Cir. 2002) (noting that "[t]he mere recital of the *Graver Tank [& Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605 (1950)] mantra that the accused device performs 'the same function, in the same way, to achieve the same result,' without

more, does not create a genuine issue of material fact as to whether an accused device infringes by equivalents” (citation and internal quotation marks omitted; alterations in original)).

Moreover, even if Plaintiffs had put forth specific evidence regarding the function-way-result test and known interchangeability, concluding that the '373 Patent covers the use of tethered fluorescent molecules employed in the Accused '373 Products would vitiate the claim limitation. As set forth in greater detail above, “an element of an accused product or process is not, as a matter of law, equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation.” *Freedman Seating*, 420 F.3d at 1358. Because the Court’s claim construction has expressly *excluded* tethered fluorescent molecules from the definition of “soluble signal” (Claim Constr. Op. 21), to hold that a tethered fluorescent molecule *is* an insubstantial change would vitiate this claim limitation. The Court therefore finds that Plaintiffs have failed to raise a disputed issue of fact as to whether the Accused '373 Products infringe the “soluble signal” limitation in Claim 1 of the '373 Patent, and, accordingly, grants Defendants’ motion for summary judgment.

V. DIRECTLY DETECTABLE LABELS

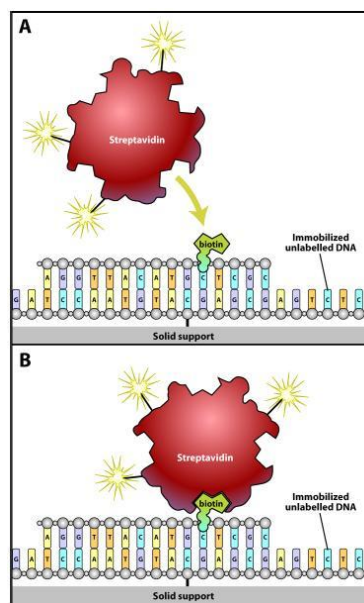
Defendants assert that they are entitled to summary judgment because, in greatly simplified terms, Claim 1 of the '824 Patent and Claim 42 of the '767 Patent do not claim the use of directly detectable labels, as are used in certain of Defendants’ products (the “Accused Labeled Products”),⁵ but only of labels that can be indirectly detected.

⁵ A complete list of the Accused Labeled Products is set forth in Exhibit 23 to the Gunther Declaration.

A. Background

The '824 and '767 Patents relate to the process of modifying nucleotides by attaching detectable labels. Because the polynucleotide sequences are so small, attaching a label allows the presence of a labeled nucleotide sequence to be more easily detected. (Claim Constr. Op. 3, 9.) For example, when using a test method such as that disclosed in the '373 Patent to determine if a DNA sample has hybridized, or bonded, with a test sequence, a detectable label must be attached to the unfixed nucleotide. (*Id.* at 19.) That label can be either “indirectly detectable” or “directly detectable.” (*Id.* at 3, 9; Def.’s Br. 5.)

An “indirectly detectable” label consists of two parts, – a handle and a larger detectable label – as shown in the following illustration:

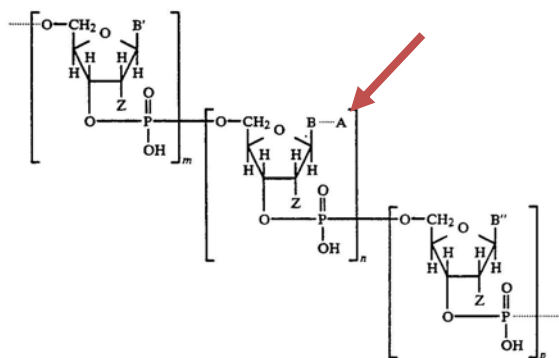


(Def.’s Br. 13) The item labeled “biotin” in panel A of the above illustration is a handle that is initially affixed to the probe. After the probe hybridizes to the target sequence, a larger molecule that is detectable and designed to bind to the handle is then introduced. The larger, detectable molecule

in the above figure is labeled “streptavidin” and bonds with the handle. (*Id.* at 12-13.)

In contrast, when using a “directly detectable” label, a detectable label is attached to the probe and no other materials need to be introduced before the presence or absence of the sequence can be detected. (*Id.*) Defendants explain that many methods for DNA testing use indirectly detectable labels instead of directly detectable labels because they are less likely to interfere with the hybridization process. (*Id.* at 13.)

Claim 1 of the '824 Patent includes the following diagram, which indicates the position of various items on the labeled nucleotide chain. The challenged portion of this claim relies in large measure on the item denoted “A,” as indicated by the arrow below:



(’824 Patent col.30-31.)⁶ Both the ’824 Patent and the ’767 Patent contain the identical claim that “A comprises at least three carbon atoms and represents at least one component of a signaling moiety capable of producing a detectable signal.”⁷

⁶ Although this illustration spans two pages in the patent, the Court combined the two separate graphics for ease of readability.

⁷ “In physical organic chemistry, moiety is generally used to signify part of a molecule.” *Moiety*, Compendium of Chemical Terminology, <http://goldbook.iupac.org/M03968.html>.

(’824 Patent col.31, ll.27-29; ’767 Patent col.30, ll.66-68.) During the claim construction proceedings, the parties vigorously disputed whether the patents cover directly detectable labels or only indirectly detectable labels. Ultimately, the Court rejected Plaintiffs’ argument that “A” could be the sole component of the signaling moiety and operate alone as a directly detectable signal. (Claim Constr. Op. 9.) The Court held: “‘A’ is but one component of a multi-component signaling moiety capable of indirect detection via an attached polypeptide.” (*Id.* at 9-10.)

B. Analysis

Defendants argue that the Accused Labeled Products do not infringe on the patents in question because those products, use a “directly detectable” fluorescent label, whereas the Court explicitly construed the patent claim to require the use of indirectly detectable labels. (*Id.* at 9-10.) Because the Court’s construction of these claims does not cover the direct detection methods employed in the Accused Labeled Products, summary judgment of no literal infringement is appropriate notwithstanding Plaintiffs’ argument that the Accused Labeled Products are “capable of” indirect detection. (Opp’n 22.) “[A] device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim.” *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1555 (Fed. Cir. 1995). Here, the claim limitations do not cover a device that uses direct detection; rather, the Court’s claim construction unambiguously limits the scope of these claims to devices that use indirect detection. (Claim Constr. Op. 9.) Accordingly, the fact that the Accused Labeled Products are capable of indirect detection is not enough to establish infringement. Plaintiffs have offered no evidence to suggest that these

products were designed or marketed to be used with indirectly detectable labels or that they are used in a manner consistent with the indirectly detectable labeling scheme disclosed in the patents. Therefore, Plaintiffs have not raised a material question of fact as to whether the Accused Labeled Products literally infringe this limitation.⁸ Because Plaintiffs do not argue that these products infringe this limitation under the doctrine of equivalents, the Court grants Defendants' summary judgment of non-infringement of Claim 1 of the '824 Patent and Claim 42 of the '767 Patent with respect to the Accused Labeled Products.

VI. ACYCLONUCLEOTIDE PRODUCTS

PerkinElmer additionally moves for summary judgment on the grounds that certain of its products that contain acycloterminals (the "Accused Acyclonucleotide Products") do not infringe Claim 42 of the '767 Patent or Claim 1 of the '824 Patent.⁹ (Def.'s Br. 16-19.) The Court proceeds to address whether these

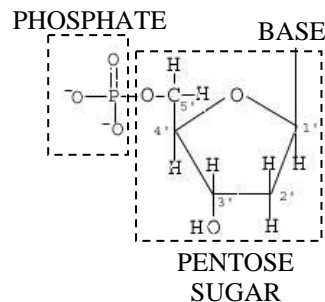
⁸ Plaintiffs assert that Amersham and PerkinElmer "sell fluorescent-labeled products that are not only 'capable of' indirect detection but actually have labels that are bound to antibodies." (Opp'n 23.) However, in support of this one-sentence argument, Plaintiffs cite only to two exhibits, which include a total of sixteen pages of highly technical scientific information about the products. (MacLean Decl. Exs. 32, 33.) When the party moving for summary judgment demonstrates the absence of a genuine issue of material fact, the opposing party "must come forward with *specific evidence* demonstrating the existence of a genuine dispute of material fact." *Brown v. Eli Lilly and Co.*, 654 F.3d 347, 358 (2d Cir. 2011) (citing *Anderson*, 477 U.S. at 249). These abstruse specification sheets, provided without any explanation or specific citation, are insufficiently particular to establish that there is a material question of fact as to whether products made by Amersham and PerkinElmer used indirectly detectable labels.

⁹ A complete list of these products is set forth in Exhibit 28 to the Gunther Declaration.

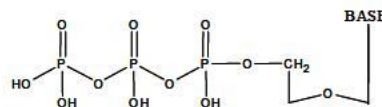
products literally infringe the asserted claims of these patents and whether they infringe under the doctrine of equivalents.

A. Background

The Accused Acyclonucleotide Products do not include solely naturally occurring nucleotides but also contain a molecule that PerkinElmer calls an "acycloterminal," to which a fluorescent label is attached. (Def.'s 56.1 ¶ 16; Pl.'s 56.1 ¶ 16; Gunther Decl. Ex. 25 ¶¶ 14-17.) Whereas naturally occurring nucleotides contain pentose sugars in a five-carbon ring structure (Def.'s Br. 17), an acycloterminal contains an "acyclic" or open sugar structure instead of a pentose sugar (*Id.* at 17-18; Decl. of Rankin Sinden, dated Dec. 13, 2011, Doc. No. 269 ("Sinden Decl."), ¶ 64). Specifically, a naturally occurring nucleotide is composed of the following general chemical structure:



(See Def.'s Br. 3.) The pentose sugar contains a carbon atom at each of the positions labeled 1' through 5' in what is essentially the shape of – as the name suggests – a pentagon. In contrast, an acycloterminal has the following chemical structure:



(Gunther Decl. Ex. 25 ¶ 14.)

B. Literal Infringement

There can be no dispute that the Accused Acyclonucleotide Products do not literally infringe Claim 1 of the '824 Patent or Claim 42 of the '767 Patent. The Court has unambiguously construed these claims to require the presence of a pentose sugar.¹⁰ (Claim Constr. Op. 7 (explaining that Plaintiffs' "contention that the claim does not specifically call for a pentose sugar is unpersuasive").) PerkinElmer has adduced evidence that the Accused Acyclonucleotide Products do not have pentose sugars but instead use acycloterminals. (Def.'s 56.1 ¶ 16; Pl.'s 56.1 ¶ 16; Gunther Decl., Ex. 25 ¶¶ 14-17.) As discussed in more detail below, while acycloterminals contain a form of sugar, they nonetheless lack the specific arrangement required by the patents. Therefore, they do not literally infringe.

In opposition, Plaintiffs' expert, Dr. Sinden, asserts that the Accused Acyclonucleotide Products are "undeniably 'comprised of' . . . both nucleotides and pentose sugars." (Sinden Decl. ¶ 63.) However, Dr. Sinden does not cite to any authority in support of this conclusory assertion. (*Id.*) Instead, Dr. Sinden

essentially acknowledges that acycloterminals themselves lack a pentose sugar but concludes that the Accused Acyclonucleotide Products nonetheless meet the claim limitations because the acycloterminals are attached to chains of nucleotides, which by definition include pentose sugars. (*Id.*; Opp'n at 26-27 (explaining that "the acyclo products are incorporated into and form an integral part of an 'oligonucleotide' sequence, which includes both multiple nucleotides and pentose sugars").)

The Court rejects this strained argument. The patent claims here deal with the narrow issue of the specific component to which a label is attached. (Claim Constr. Op. 6-8.) Accordingly, it is irrelevant whether any *part* of the oligonucleotide chain contains a pentose sugar. To literally meet the claim limitations, the label must be attached to an item that has a pentose sugar. Because there is no evidence to suggest that the label is attached to an item with a pentose sugar in the Accused Acyclonucleotide Products, the Court finds that summary judgment of no literal infringement is appropriate.

C. Doctrine of Equivalents

Even if not literally infringing, the Accused Acyclonucleotide Products may still be found to infringe on the patents under the doctrine of equivalents. As set forth above, this doctrine provides that "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson*, 520 U.S. at 21.

Dr. Sinden explains, in some technical detail, that the pentose sugars disclosed in

¹⁰ Plaintiffs argue that Judge Sprizzo's claim construction opinion did not specifically construe Claim 1 of the '824 Patent; rather it only construed Claim 42 of the '767 Patent. (Opp'n 26 n.18.) However, these patents share a common specification and, as Defendants note, Claim 1 of the '824 Patent includes a picture of a labeled nucleotide with a pentose sugar. (Reply 8; '824 Patent cols.30-31.) Although Plaintiffs assert that Claim 1 of the '824 Patent, which contains an illustration of a pentose sugar, need not contain a pentose sugar, they offer no hint as to why that would be nor any citation to support that proposition. Because this patent claim unambiguously contains a pentose sugar and Plaintiffs offer no explanation for why the Court could conclude that it need not contain a pentose sugar, the Court construes this claim also to require the presence of a pentose sugar.

the patents and the acycloterminals used in the Accused Acyclonucleotide Products perform the same function of facilitating the incorporation of an additional labeled nucleotide. (Sinden Decl. ¶ 64.) Additionally, according to Dr. Sinden, both perform this function the same way, in that the sugar moiety of the base to be incorporated bonds with the 3' end group of the last base at the end of the sequence to be extended/labeled.¹¹ (*Id.*) The result is thus the same because both oligonucleotide sequences are extended by one base. (*Id.*) Based on Dr. Sinden's declaration, the Court finds that there is, at the very least, a disputed issue of material fact as to whether the acyclic sugars used in the Accused Acyclonucleotide Products are insubstantially different from the pentose sugars disclosed in Claim 1 of the '824 Patent or Claim 42 of the '767 Patent. Accordingly, summary judgment of non-infringement is not proper with respect to these claims.

Furthermore, a finding of equivalence in this circumstance would not vitiate the claim limitation as construed by the Court. "A holding that the doctrine of equivalents cannot be applied to an accused device because it 'vitiates' a claim limitation is nothing more than a conclusion that the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1018-19 (Fed. Cir. 2006). The Court does not agree with Defendants that a finding of equivalence would vitiate the

Court's claim construction, which required that the "'nucleotide or oligo- or polynucleotide sequence' at issue be comprised of otherwise naturally-occurring nucleotides which have been modified solely by the addition of at least one label." (Claim Constr. Op. 7.) Although the acycloterminals used in the Accused Acyclonucleotide Products have been modified by adding a label *and* breaking apart the naturally occurring pentose sugar by removing two carbon atoms together with their associated oxygen and hydrogen atoms (Reply 8), infringement under the doctrine of equivalents is not "always foreclosed whenever a claim limitation does not literally read on an element of an accused device," *DePuy Spine*, 469 F.3d at 1018. In this case, although the claims are indisputably limited to nucleotides with pentose sugars and do not embrace acycloterminals, the Court cannot conclude that no reasonable jury could find that the Accused Acyclonucleotide Products nevertheless infringe under the doctrine of equivalents.

While Defendants place great emphasis on the Federal Circuit's decision in *Durel Corp. v. Osram Sylvania, Inc.*, 256 F.3d 1298 (Fed. Cir. 2001), the factual situation presented here is readily distinguishable. In *Durel*, the court concluded that a finding of equivalence would vitiate the limitation "oxide coating," which the court construed to consist of a binary compound when the accused products contained a third element. *Id.* at 1305. In contrast, although the Court's construction of the claim clearly excludes acycloterminals, it does not so narrowly cabin the claims that finding equivalence would vitiate the limitation relating to pentose sugars. Instead, the situation presented in this case is more similar to that in *DePuy Spine*, where the Federal Circuit reversed a district court's grant of summary judgment of non-

¹¹ The 3' end group is noted with the "3'" in the illustration of a nucleotide on the previous page.

infringement under the doctrine of equivalents and held that there was a question of fact as to whether the “conically-shaped” portion of the accused products was equivalent to the “spherically-shaped” item claimed in the patent. 469 F.3d at 1020. Although the accused product was of a different shape than that called for in the claim limitations, the Federal Circuit nonetheless concluded that a finding of equivalence would not vitiate the claim limitations and that summary judgment was not possible. *Id.* Similarly, here, while the acycloterminators are unquestionably different from nucleotides with pentose sugars, a finding of equivalence would not vitiate the claim limitations.

Moreover, Defendants’ reliance on certain other patents, which discuss the relative benefits of nucleotide sequences that use acycloterminators instead of pentose sugars, does not alter the Court’s conclusion. Although Defendants assert that certain “DuPont” patents disclose that nucleotides with acycloterminators are more easily synthesized than those having pentose sugars (Reply 9), these patents do not compel a finding that the accused products are not substantially similar. *Cf., e.g., Alcohol Monitoring Sys., Inc. v. Actsoft, Inc.*, 414 F. App’x 294, 300 (Fed. Cir. 2011) (reversing grant of summary judgment of non-infringement because a reasonable jury could conclude that the accused product performs substantially the same function, in substantially the same way, to achieve substantially the same result as the patent claim). Accordingly, summary judgment in favor of Defendants is inappropriate.

Finally, the Court concludes that Plaintiffs are not estopped from asserting infringement under the doctrine of equivalents by virtue of representations that were made while prosecuting these patents. “[P]rosecution history estoppel limits the

range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent.” *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1367 (Fed. Cir. 2007) (citation and internal quotation marks omitted); *accord Festo Corp.*, 535 U.S. at 733. For instance, if the patentee originally sought to have a patent include a particular feature but abandoned pursuit of that feature during prosecution by arguing that it was not covered by the patent, argument-based prosecution history estoppel may prevent the patentee from later claiming that the jettisoned feature is covered by the patent. *See Ottah v. First Mobile Techs.*, No. 10 Civ. 7296 (CM), 2012 WL 527200, at *7 (S.D.N.Y. Feb. 17, 2012) (citing *Festo Corp.*, 535 U.S. at 733). However, “[t]o invoke argument-based estoppel . . . the prosecution history must evince a clear and unmistakable surrender of subject matter.” *Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, 460 F.3d 1349, 1364 (Fed. Cir. 2006) (citation and internal quotation marks omitted). Additionally, “[c]lear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may also create an estoppel,” *Southwall Techs. Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1583 (Fed. Cir. 1995), because “[t]he relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter,” *Conoco*, 460 F.3d at 1364 (citation and internal quotation marks omitted).

Here, Defendants assert that Plaintiffs are estopped from arguing infringement under the doctrine of equivalents because they stated that the invention was “nucleotide-based” in order to distinguish prior art that involved labeled structures with some, but not all, components of a naturally occurring nucleotide. (Def.’s Br. 18-19; Reply 11.) Specifically, during

prosecution of the '767 Patent, Plaintiffs distinguished certain prior art by arguing that it contained no teaching or suggestion of "nucleotides or chemically labeled nucleotides, either pyrimidine nucleotides or purine nucleotides." (Gunther Decl. Ex. 29 at 3.)¹² This statement, however, does not unmistakably surrender claim to products with acycloterminators, in which the nucleotides are additionally modified by removing molecules from the pentose sugars. *Cf. Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1177-78 (Fed. Cir. 2008) (holding that the patentee's reference to "common cylindrical plane" in the prosecution history . . . did not disclaim any subject matter that was otherwise within the scope of the claim language, but merely explained, in more explicit terms, what the claims already covered"). The Court finds that this reference to nucleotides did not disclaim material but rather clarified what the patent covered and certainly does not evidence a "clear and unmistakable" surrender of modified nucleotides, let alone the acycloterminator arrangement used in the Accused Acyclonucleotide Products.

Additionally, Defendants rely on statements that were made during the prosecution of the '955 Patent, that distinguished prior art references by asserting that the patent claims "do not refer to or suggest applicants' nucleotides because they only refer to bases without sugars." (Gunther Decl. Ex. 30 at 26.) However, even if the statements made during prosecution of a separate patent application could be a basis for limiting the scope of the claims of the '824 and '767 Patents, the Court finds that these statements do not rise

to the level of a clear and unmistakable surrender of all sugars other than naturally occurring pentose sugars. While a competitor might reasonably believe that a "sugar" is required, nothing in these statements suggests that acyclosugars, which Defendants concede are a form of sugar (MacLean Decl. Ex. 34 at 109:11-19), were surrendered. Accordingly, the Court finds that Plaintiffs are not barred by the doctrine of prosecution history estoppel from asserting infringement under the doctrine of equivalents.

* * *

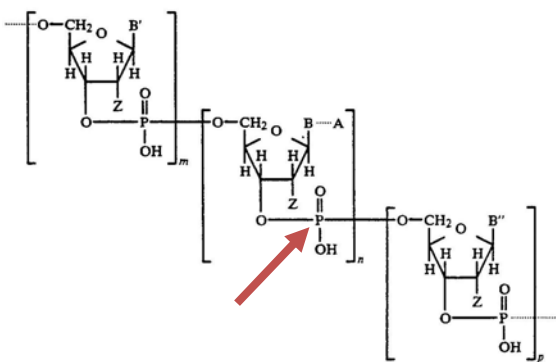
Based on the foregoing analysis, the Court finds that, although the Accused Acyclonucleotide Products do not literally infringe the terms of the '824 and '767 Patents, there remains a material question of fact as to whether they are insubstantially different from the matters claimed in these patents. Therefore, the Court denies Defendant's motion for summary judgment of non-infringement with respect to the Accused Acyclonucleotide Products.

VII. DIDEOXYNUCLEOTIDES

PerkinElmer further argues that it is entitled to summary judgment of non-infringement of Claim 1 of the '824 Patent with respect to its products containing dideoxynucleotide monomers (the "Accused Dideoxy Products").¹³ (Def.'s Br. 21-22.) This claim contains the following illustration, representing a nucleotide chain:

¹² Defendants' brief cites to Exhibit 19 of the Gunther Declaration in support of these assertions. However, it appears that Defendants intended to refer to Exhibit 29 of the Gunther Declaration.

¹³ A complete list of the Accused Dideoxy Products is set forth in Exhibit 34 to the Gunther Declaration.



(’824 Patent cols.30-31.)¹⁴ In this figure, the variables m , n , and p are integers which represent the number of times the bracketed nucleotide they label repeat. (’824 Patent col.31 ll.38-40.)

An oligonucleotide chain, such as DNA, has two ends – the 5’ end and the 3’ end. (Sinden Decl. ¶ 24.) In DNA, “the 5’ end generally contains a phosphate group (-PO₄), while the 3’ end typically contains a 3’ hydroxyl (-OH).” (*Id.*)

PerkinElmer argues that the Accused Dideoxy Products do not infringe because the ’824 Patent claims only the situation where the 3’ position of the labeled nucleotide (indicated by the arrow in the diagram above) includes a phosphate group while the Accused Dideoxy Products have a hydrogen atom at that position. (Def.’s Br. 21-22.) Indeed, Plaintiffs’ expert, Dr. Sinden, concedes that if the patent claim requires a phosphate at that location, then the Accused Dideoxy Products do not fall within the literal scope of the claim. (Supp. Decl. of Robert J. Gunther, Jr., dated Jan. 13, 2012, Doc. No. 273 (“Supp. Gunther Decl.”), Ex. 8 at 157:3-18.)

However, the patent expressly claims the situation “wherein m , n and p are integers,

provided that m and p are not simultaneously 0 and provided further n is never 0.” (’824 Patent col.31 ll.38-40 (emphasis added); *see* Sinden Decl. ¶ 69.) As explained by Dr. Sinden, persons of skill in the art would understand that this claim encompasses a circumstance where “ $p = 0$,” and there is no nucleotide labeled with the subscript p (the “ p -nucleotide”). (Sinden Decl. ¶¶ 67, 69 (emphasis added).) Dr. Sinden further opines that persons of skill in the art would understand that, in the event there is no p -nucleotide, the nucleotide denoted with the subscript n (the n -nucleotide) would not contain a phosphate group at the location indicated by the arrow, but would instead contain a hydrogen atom. (*Id.*) Accordingly, Dr. Sinden opines that the products meet all limitations of the ’824 Patent. (*Id.* ¶ 69.)

In conclusory fashion, without any citation to a relevant portion of the record, PerkinElmer asserts that even in situations where the p -nucleotide is not present, *i.e.*, $p = 0$, the patent still requires that the n -nucleotide have a 3’ phosphate group, and the only change would be that there is no p -nucleotide attached to it. (Reply 6.) PerkinElmer does not respond to Dr. Sinden’s assertion that if the p -nucleotide is not present – which is clearly a situation contemplated and claimed in the patent – a person of reasonable skill in the art would understand that the n -nucleotide at the end of the strand would not contain a phosphate. Accordingly, there is a material question of fact as to whether a person of ordinary skill in the art would understand that, in situations when “ $p = 0$,” the phosphate group in the nucleotide at the end of a chain, as indicated by the arrow in the diagram above, may not be present and, instead, may be replaced by a hydrogen atom.

PerkinElmer’s reliance on other portions of the patent, which explicitly disclose

¹⁴ Although this illustration spans two pages in the patent, the Court combined the two separate graphics for ease of readability.

variables at different locations of the structures and set forth different molecules that may be present, does not suggest otherwise. (*See* Reply 6.) To be sure, Plaintiffs' failure to explicitly disclose that the phosphate group would be replaced in the event the *p*-nucleotide is not present – when it did so elsewhere in the patent – is some evidence suggesting that the Accused Dideoxy Products are outside the scope of this claim. Nonetheless, whether a person of ordinary skill in the art would understand that the phosphate group could be replaced by a hydrogen atom is a question of fact that the Court cannot resolve on this motion for summary judgment. Accordingly, the Court denies Defendants' motion for summary judgment of non-infringement with respect to whether the Accused Dideoxy Products infringe Claim 1 of the '824 Patent.

VIII. DIG 5' END LABELING SETS

Defendant Roche argues that it is entitled to summary judgment that its DIG 5' End Labeling Sets¹⁵ do not infringe Claim 1 of the '824 Patent or Claim 42 of the '767 Patent. (Def.'s Br. 20-21.) In their opposition, Plaintiffs fail to respond to this point or address Roche's specific argument with respect to these products. (*See* Reply 12 n.12.) Accordingly, after a careful review of the pertinent portions of the record, the Court concludes that there is no material question of fact that the DIG 5' End Labeling Sets do not infringe Claim 1 of the '824 Patent or Claim 42 of the '767 Patent, either literally or under the doctrine of equivalents. Therefore, summary judgment of non-infringement in favor of Roche with respect to these products is appropriate.

IX. LANHAM ACT & CONTRACT CLAIMS

Based on Defendants' representations and arguments (Tr. of Aug. 25, 2011 Conf. ("Conf. Tr."), 20), the Court expressly limited the scope of the instant motion to patent issues when it set a briefing schedule (Order of Aug. 25, 2011 (Doc. No. 247)). However, Defendants have also moved for summary judgment on Plaintiffs' claim for trademark infringement under the Lanham Act. Plaintiffs did not respond to Defendants' Lanham Act arguments other than to note that they were outside the scope of the briefing that the Court had permitted at this time. (Opp'n 1 n.2.) Accordingly, the Court denies Defendants' motion for summary judgment on the Lanham Act claim without prejudice to renewal.

Similarly, Roche and PerkinElmer argue that they are entitled to summary judgment of non-infringement with respect to certain products that were produced pursuant to distributor agreements with Plaintiffs. Although their claim is more closely related to patent issues than the Lanham Act claim because it relates to infringement, the Court finds that it is nonetheless beyond the scope of the briefing that was ordered by the Court. Resolution of these claims will turn almost entirely on issues of contract interpretation, which Defendants represented they would not pursue in the course of the instant motion. (Conf. Tr. 20 (distinguishing "contract issues" from the "patent" issues to be raised in the initial round of briefing).) Therefore, the Court denies Roche and PerkinElmer's motion for summary judgment on the ground that the production of certain products was authorized by agreement without prejudice to renewal.

¹⁵ These products are alternatively referred to as the "Genius 5' End Labeling Sets" by Plaintiffs.

X. CONCLUSION

For the foregoing reasons, Defendants' motion for summary judgment is granted in part and denied in part. Specifically, Defendants' motion for summary judgment of non-infringement is granted with respect to the Accused Labeled Products, the DIG 5' Products, and the Accused '373 Products. Defendants' motion is denied with respect to the Accused Acyclonucleotide Products and the Accused Dideoxy Products. Defendants' motion for summary judgment on the Lanham Act claims is denied without prejudice, as is Defendants' motion for summary judgment of non-infringement on the basis that certain products were produced with Plaintiffs' authorization.

IT IS HEREBY ORDERED THAT the parties shall submit a joint letter by October 19, 2012, setting forth a proposal for what the next steps in this matter should be.

The Clerk of Court is respectfully requested to terminate the motion pending at Doc. No. 251.

SO ORDERED.


RICHARD J. SULLIVAN
United States District Judge

Dated: September 21, 2012
New York, New York

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